# OFFICE OF SPECIAL MASTERS

(Filed: September 27, 2006)

DO NOT PUBLISH

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| [REDACTED], | ) | |
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| Petitioner, | ) | |
| | ) | |
| v. | ) | No. [REDACTED]V |
| | ) | Entitlement; Hepatitis B vaccine; |
| SECRETARY OF | ) | Neutropenia; Arthritis; |
| HEALTH AND HUMAN SERVICES, | ) | Witness Credibility |
| | ) | |
| Respondent. | ) | |
| | ) | |

## DECISION[1]

Petitioner, [REDACTED], seeks compensation under the National Vaccine Injury Compensation Program (Program).[2] Ms. [REDACTED] alleges that she suffers neutropenia[3] and arthritis that are related to a Hepatitis B vaccination that she received on April 28, 1998. *See generally* Prehearing Memorandum (P. Memo), filed August 19, 2005; *see also* Amended Petition (Am. Pet.), filed April 13, 2006 (asserting a significant aggravation claim). According to Ms. [REDACTED], her "first severe and marked problem" occurred in August 1998 when she "contracted a [sic] pneumonia." Petitioner's exhibit (Pet. ex.) 13, ¶ 3. Later, Ms. [REDACTED] states, she "began to experience significant knee pain." *Id.*, ¶ 4. Then, Ms. [REDACTED] maintains, her "health" became "progressively worse." *Id.*, ¶ 8. Ms. [REDACTED] recounts that

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[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

[3] Neutropenia is "a decrease in the number of neutrophils in the blood." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1260 (30th ed. 2003).

she developed frequent "flu-like symptoms," *id.*, ¶¶ 6, 8; "persistent canker sores" and fatigue accompanied by a constant, "low grade fever." *Id.*, ¶ 8.

The special master convened a hearing. Ms. [REDACTED] and Ariel Distenfeld, M.D. (Dr. Distenfeld),[4] testified during Ms. [REDACTED]'s case-in-chief. Gregory H. Reaman, M.D. (Dr. Reaman),[5] testified during respondent's rebuttal case.

## THE STATUTORY SCHEME

Ms. [REDACTED] understands that she pursues necessarily her claim upon an actual causation theory. *See* P. Memo at 11. The same legal principles for actual causation that apply in traditional tort litigation apply in Program cases. Thus, to prevail, Ms. [REDACTED] must demonstrate by the preponderance of the evidence that (1) "but for" the administration of her April 28, 1998 Hepatitis B vaccination, she would not have been injured, and (2) her April 28, 1998 Hepatitis B vaccination "was a substantial factor in bringing about" her injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See In re Winship,* 397 U.S. 358, 371-72 (1970)(Harlan, J., concurring)(quoting F. JAMES, CIVIL PROCEDURE 250-51 (1965)). Mere conjecture or speculation will not meet the preponderance of evidence standard. *See Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612, 624 (1995), *aff'd*, 73 F.3d 381 (1995).

A simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for an injury, are patently insufficient to prove legal cause. *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992). Rather, Ms. [REDACTED] must present "a medical theory," supported by "[a] reliable medical or scientific explanation," establishing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Id.* at 1148; *see also Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994)(citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)); *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed.

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[4] Dr. Distenfeld received his medical degree from New York University School of Medicine. *See* Petitioner's Notice of Filing, filed January 29, 2004, Attachment 3 at 1. He is Chief of the Division of Hematology at Cabrini Medical Center in New York, New York. *See* Transcript (Tr.) at 45. He holds an academic appointment as a clinical professor at New York University School of Medicine. *See id.* He is certified in internal medicine and in hematology by the American Board of Internal Medicine. *See* Petitioner's Notice of Filing, filed January 29, 2004, Attachment 3 at 2.

[5] Dr. Reaman received his medical degree from Loyola University Chicago Stritch School of Medicine. Respondent's exhibit (R. ex.) B at 1. He is Chairman of the Oncology Group at the Children's National Medical Center in Washington, D.C. Tr. at 112. He holds an academic appointment as a professor of pediatrics at The George Washington University School of Medicine and Health Sciences. R. ex. B at 2. He is certified in pediatrics and in hematology/oncology by the American Board of Pediatrics. R. ex. B at 1.

Cir. 2005); *Capizzano v. Secretary of HHS (Capizzano III)*, 440 F.3d 1317 (Fed. Cir. 2006). "The analysis undergirding" the medical or scientific explanation must "fall within the range of accepted standards governing" medical or scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Ms. [REDACTED]'s medical or scientific explanation need not be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. But, Ms. [REDACTED]'s medical or scientific explanation must be "logical" and "probable," given "the circumstances of the particular case." *Id.* at 548-49.

## DISCUSSION

Congress prohibited special masters from awarding compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a). Numerous cases construe § 300aa-13(a). The cases reason uniformly that "special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone." *Raley v. Secretary of HHS*, No. 91-0732V, 1998 WL 681467, at *9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998); *see also Camery v. Secretary of HHS*, 42 Fed. Cl. 381, 389 (1998).

Ms. [REDACTED] attributes two distinct conditions to her April 28, 1998 Hepatitis B vaccination: neutropenia–a hematological disorder–and arthritis–an inflammatory rheumatological disorder. *See generally* P. Memo. Ms. [REDACTED] relies upon Dr. Distenfeld's opinion to support a causal association between her April 28, 1998 Hepatitis B vaccination and her neutropenia. *See, e.g.*, P. Memo at 6. However, Dr. Distenfeld is not a rheumatologist. Tr. at 47. In his medical practice, he does not diagnose or treat patients with rheumatological diseases or with arthritis. *Id.* Indeed, he concedes that he is not qualified to opine regarding a causal association between Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination and Ms. [REDACTED]'s arthritis. *See* Tr. at 59-60; *see also* Tr. at 95. As a consequence, Ms. [REDACTED] relies solely upon her medical records to support a causal association between her April 28, 1998 Hepatitis B vaccination and her arthritis.

The special master engages usually in a thorough, critical, intellectual analysis of the facts, the medical evidence and the medical testimony under the actual causation standard. *See, e.g.*, *Malloy v. Secretary of HHS*, No. 99-0193V, 2003 WL 22424968 (Fed. Cl. Spec. Mstr. Aug. 6, 2003); *Gall v. Secretary of HHS*, No. 91-1642V, 1999 WL 1179611 (Fed. Cl. Spec. Mstr. Oct. 31, 1999). However, after considering carefully the record as a whole, the special master determines that a comprehensive opinion is not necessary in this case. Rather, the special master identifies four pointed, dispositive issues. First, the special master discusses his impression of Ms. [REDACTED]'s credibility. Second, the special master discusses his confidence in Dr. Distenfeld's presentation. Third, the special master discusses the sufficiency of Ms. [REDACTED]'s medical records in establishing a causal association between Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination and Ms. [REDACTED]'s arthritis. Finally, the special master discusses Ms. [REDACTED]'s alternate, significant aggravation theory.

Ms. [REDACTED]'s Credibility

The United States Court of Appeals for the Federal Circuit (Federal Circuit) counsels that "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras v. Secretary of HHS*, 993 F.2d 1525, 1528 (1993). The Federal Circuit explains that "generally contemporaneous" medical records "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Id.* Thus, the Federal Circuit recognizes that "[w]ith proper treatment hanging in the balance, accuracy has an extra premium." *Id.* Likewise, the Federal Circuit counsels that "oral testimony in conflict with contemporaneous documentary evidence deserves little weight." *Id.*, citing *United States Gypsum Co.*, 333 U.S. 364, 396 (1947).

Ms. [REDACTED] asserts that she was perfectly well until August 1998. *See* Pet. ex. 13, ¶¶ 1, 3-8; Tr. at 12. Since August 1998, according to Ms. [REDACTED], her "health has gotten progressively worse." Pet. ex. 13, ¶ 8; *see also* Tr. at 15-18. However, Ms. [REDACTED]'s medical records from 1998 belie the chronology of the putative decline of her health that Ms. [REDACTED] advances in this litigation.

On April 28, 1998, Ms. [REDACTED] presented to The City of New York Department of Health and Mental Hygiene Riverside Clinic for a "S[exually]T[ransmitted]D[isease] exam." Pet. ex. 31 at 4. She complained of a "2nd episode" of an oral "sore." *Id.* at 7. The physician who examined Ms. [REDACTED] observed two "ulcers." *Id.* at 4. It appears that the physician believed that Ms. [REDACTED] was exhibiting a recurrent condition. *See id.*

Moreover, in early September 1998, Ms. [REDACTED] reported to *three* separate providers a variety of symptoms that she estimated had been present for *six months*, a period long before August 1998. On September 1, 1998, Ms. [REDACTED] told Jonathan L. Glashow, M.D. (Dr. Glashow), that she had experienced "pains" in both knees "for about six months" that "developed" into "acute pain in and around" her right "knee cap area." Pet. ex. 7 at 1. According to Dr. Glashow, Ms. [REDACTED] described "abrupt shooting pains" and "irritation" in the "patellofemoral area." *Id.* Dr. Glashow suspected "a patellofemoral[-]type problem." *Id.* On September 3, 1998, Ms. [REDACTED] told G. Avaz, M.D. (Dr. Avaz), during a "[n]ew w[or]kup" at Columbia Presbyterian Medical Center that "for [the] last 6 months," she had experienced "episodes of [questionable] sore throat, tactile temp[erature] [for] 2-3 days, fatigue" and "recurrent cold sores." Pet. ex. 6 at 1. Based upon Ms. [REDACTED]'s "multiple nonsp[ecific] complaints," Dr. Avaz suspected that Ms. [REDACTED] had suffered "recurrent viral inf[ectio]ns." *Id.* at 2. On September 9, 1998, Ms. [REDACTED] told a physical therapist that for about six months, she had "noticed minor discomfort in [her] [right] knee [after]" running. Pet. ex. 12 at 2. Ms. [REDACTED] related that the pain increased "progressively" to "2 episodes of sharp pain" that "woke" her "out of sleep." *Id.*

Ms. [REDACTED] is intelligent, educated and articulate. She is able to comprehend questions. She is able to respond appropriately to questions. She professes a keen interest in her health. Thus, the dichotomy between details that Ms. [REDACTED] related to *three* separate providers in September 1998 during the course of diagnosis and treatment and her current

recollection is particularly jarring. On its face, the dichotomy compels the special master to conclude that Ms. [REDACTED]'s current recollection is not correct.

At hearing, Ms. [REDACTED] acknowledged the dilemma that her recitations of her medical history, as reflected in her medical records from 1998, differ obviously from her current recitation of her medical history. *See, e.g.*, Tr. at 28-32. Ms. [REDACTED] offered several explanations for the conflict between the medical histories from 1998 and her current recollection. Ms. [REDACTED] suggested that cues from at least one provider prompted her to give an inaccurate account of the duration of her symptoms. *See, e.g.*, Tr. at 28. Ms. [REDACTED] suggested also that her pain and "medication . . . like, Advil," induced "a daze," preventing her from "thinking" coherently about the duration of her symptoms. Tr. at 30; *see also* Tr. at 106. Ms. [REDACTED] suggested finally that in September 1998, she "really didn't think it was important when exactly the symptoms began." Tr. at 32.

In the special master's view, Ms. [REDACTED]'s explanations are wholly incredible. First, medical professionals do not have a vested interest in encouraging patients to recount false information about their condition. Rather, as the Federal Circuit held in *Cucuras*, just the opposite is true. Thus, the special master does not believe that any of Ms. [REDACTED]'s providers urged her in any way to give a wrong duration of her symptoms. Second, Dr. Avaz's September 3, 1998 examination record appears very complete. Dr. Avaz's September 3, 1998 examination record does not indicate that Ms. [REDACTED] was in any acute distress. And, Dr. Avaz did not express the slightest concern regarding Ms. [REDACTED]'s reliability as a historian. Thus, the special master considers the suggestion that Ms. [REDACTED] was unable to communicate a proper chronology of her symptoms to Dr. Avaz to be absurd. Third, Ms. [REDACTED]'s assertion that in September 1998, she did not believe that she needed to report reliable information about the duration of her symptoms to her medical providers runs counter again to the Federal Circuit's observation that "accuracy has an extra premium" in the context of "diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528. When Ms. [REDACTED] sought medical treatment in September 1998, she estimated that the constellation of her symptoms had been present for six months. Now, Ms. [REDACTED] desires to disavow her statements from 1998. The special master concludes simply that Ms. [REDACTED] is not a persuasive witness. As a consequence, the special master finds that Ms. [REDACTED]'s current recollection about the onset of her myriad of symptoms in 1998 constitutes nothing more than fanciful revision.

Ms. [REDACTED]'s medical records from April 28, 1998, reveal that before her April 28, 1998 Hepatitis B vaccination, Ms. [REDACTED] was suffering certainly a symptom–"persistent canker sores"–that she insists arose only after August 1998. *See* Pet. ex. 13, ¶ 8. Moreover, Ms. [REDACTED]'s medical records from early September 1998 reveal that Ms. [REDACTED] placed consistently the onset of a constellation of other symptoms–symptoms that she insists arose only in August 1998 or later, *see* Pet. ex. 13, ¶¶ 4, 8; Tr. at 15-18–at approximately six months before early September 1998. A fair, literal interpretation of the approximate six-month period that Ms. [REDACTED] recalled in early September 1998 includes clearly the earliest days of March 1998–a span of eight full weeks before Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination.

A portion of Dr. Avaz's September 3, 1998 notes correlates especially well with information in Ms. [REDACTED]'s medical records from April 28, 1998. On September 3, 1998, Ms. [REDACTED] told Dr. Avaz that she had exhibited "recurrent cold sores," among other symptoms, "for [the] last 6 months." Pet. ex. 6 at 1. Ms. [REDACTED]'s medical records confirm that Ms. [REDACTED]'s "cold sores" preceded Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination. *See* Pet. ex. 31 at 4. Thus, Ms. [REDACTED]'s medical records support rationally a conclusion that Ms. [REDACTED] experienced also the other symptoms, including "episodes of [questionable] sore throat, tactile temp[erature] [for] 2-3 days" and "fatigue" before her April 28, 1998 Hepatitis B vaccination. Pet. ex. 6 at 1. In any event, Ms. [REDACTED]'s medical records do not support at all a contention that Ms. [REDACTED]'s constellation of symptoms occurred first in early August 1998 or later. Thus, the special master determines that it is more likely than not that along with her recurrent cold sores, Ms. [REDACTED] suffered "episodes of [questionable] sore throat, tactile temp[erature] [for] 2-3 days" and "fatigue" preceding her April 28, 1998 Hepatitis B vaccination. Pet. ex. 6 at 1. In addition, the special master determines that it is more likely than not that Ms. [REDACTED] experienced knee pain preceding her April 28, 1998 Hepatitis B vaccination. *See, e.g.*, Pet. ex. 7 at 1; 12 at 2.

Neutropenia/Dr. Distenfeld's Opinion

Extremely troubling aspects of Ms. [REDACTED]'s credibility aside, the special master decides ultimately Ms. [REDACTED]'s claim regarding neutropenia based upon his assessment of Dr. Distenfeld's opinion. The special master observed closely Dr. Distenfeld during direct examination and cross-examination. In addition, the special master interrogated intently Dr. Distenfeld.

Dr. Distenfeld is seemingly a fine gentleman. And, Dr. Distenfeld possesses certainly appropriate credentials in hematology to offer an expert opinion regarding the potential association between vaccines and neutropenia. Nevertheless, given circumstances that are peculiar to this case, the special master accords Dr. Distenfeld's opinion no evidentiary weight.

In his initial affidavit, Dr. Distenfeld declared:

> In preparation for this statement[,] I have examined [REDACTED]'s medical records by various physicians and providers, dating from 1992 through the present.

Petitioner's Notice of Filing, filed January 29, 2004, Affidavit of Ariel Distenfeld, M.D., ¶ 5. During direct examination, Dr. Distenfeld testified that he reviewed Ms. [REDACTED]'s medical records. *See* Tr. at 50; *see also* Tr. at 56. *However, during examination by the special master, Dr. Distenfeld admitted that he inspected "very few pages" of Ms. [REDACTED]'s "original medical records."* Tr. at 84. Indeed, Dr. Distenfeld could not identify readily the medical records that he professed to

have read. *See, e.g.*, Tr. at 64, 84, 93. Rather, Dr. Distenfeld stated that he based his opinion upon "a history" that "was provided to" him. Tr. at 83-84.

The special master does not know who prepared the "history" that Dr. Distenfeld relied upon to render his opinion. The special master does not know the full contents of the "history" that Dr. Distenfeld relied upon to render his opinion. Thus, the special master cannot judge the validity of the "history" that Dr. Distenfeld relied upon to render his opinion. But, the special master knows without doubt that Dr. Distenfeld did not formulate his opinion upon an independent, objective appraisal of Ms. [REDACTED]'s medical history developed through his thorough review of Ms. [REDACTED]'s medical records.

A colloquy between the special master and Dr. Distenfeld highlights the fallacy of Dr. Distenfeld's methodology. Dr. Distenfeld assumed that Ms. [REDACTED] "was okay" before her April 28, 1998 Hepatitis B vaccination simply because Ms. [REDACTED] asserted that her condition began in August 1998. Tr. at 91-92; *see also* Tr. at 68. Dr. Distenfeld did not "have an immediate recollection of" Dr. Avaz's September 3, 1998 notes. Tr. at 93. However, after perusing Dr. Avaz's September 3, 1998 notes, Dr. Distenfeld agreed that he "might have to assume that [Ms. [REDACTED]] had some symptoms prior to" the April 28, 1998 Hepatitis B vaccination. Tr. at 94. Dr. Distenfeld conceded that the presence of some symptoms "prior to the vaccination" would undermine unquestionably his opinion. *Id.*

The special master has found as a matter of fact that Ms. [REDACTED] exhibited numerous symptoms, including recurrent cold sores, "episodes of [questionable] sore throat, tactile temp[erature] [for] 2-3 days" and "fatigue," Pet. ex. 6 at 1, as well as knee pain, *see, e.g.*, Pet. ex. 7 at 1; 12 at 2, before her April 28, 1998 Hepatitis B vaccination. Thus, Dr. Distenfeld's opinion, based upon Dr. Distenfeld's assumption that Ms. [REDACTED] "was okay" before her April 28, 1998 Hepatitis B vaccination, Tr. at 91-92, is essentially worthless to the special master. Moreover, contrary to his affidavit statement and to his direct testimony, Dr. Distenfeld admitted that he did not review all of Ms. [REDACTED]'s medical records. Therefore, the special master does not trust Dr. Distenfeld's opinion in this case. As a consequence, the special master does not credit Dr. Distenfeld's opinion.

The special master recognizes that Dr. Distenfeld proffered an unsolicited supplemental affidavit in May 2006. *See* Pet. ex. 32. In the affidavit, Dr. Distenfeld advances his view that except for "two small canker sores on her inner lip," Ms. [REDACTED] "was in good health prior to" her April 28, 1998 Hepatitis B vaccination. Pet. ex. 32 at 1. Dr. Distenfeld bases his conclusion on "new records," namely The City of New York Department of Health and Mental Hygiene Riverside Clinic notes from April 28, 1998. *Id.* Then, according to Dr. Distenfeld, Ms. [REDACTED] "developed symptoms of pneumonia in August of 1998" followed by "recurrent symptoms of sore throat and fatigue." *Id.*

The special master discounts Dr. Distenfeld's supplemental affidavit. At the outset, the special master determines that Dr. Distenfeld's supplemental affidavit does not rehabilitate the

special master's rational, substantive concerns about Dr. Distenfeld's role as an expert in this case, and, more particularly, about Dr. Distenfeld's hearing testimony. Likewise, in his supplemental affidavit, Dr. Distenfeld does not address Dr. Avaz's September 3, 1998 notes that the special master discussed with Dr. Distenfeld at hearing. *See* Tr. at 93-94. Under Federal Circuit precedent, Dr. Avaz's September 3, 1998 notes are highly probative. Therefore, the special master concludes that Ms. [REDACTED] has not established through Dr. Distenfeld's opinion that her April 28, 1998 Hepatitis B vaccination is the legal cause of her neutropenia.

Arthritis/Ms. [REDACTED]'s Medical Records

The statute enacting the Program requires the special master to "consider . . . any diagnosis, conclusion, [or] medical judgment which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury [or] condition." § 300aa-13(b)(1). The rationale is sound. As the Federal Circuit noted in *Capizzano III*, a treating physician's clinical observations can be "quite probative" because treating physicians "are likely to be in the best position to determine" a cause for a petitioner's condition. *Capizzano III*, 440 F.3d at 1326; *see also Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387418, at *16 (Fed. Cl. Spec. Mstr. Mar. 30, 2001)(A treating physician's "assessments of the cause of the injury, just as any other expert's [assessments] in the case, may be probative if the opinions expressed are relevant, rational, cogent, and well-supported."). However, the Act provides also that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master." § 300aa-13(b)(1). The rationale is equally sound. A treating physician's opinion regarding causation may not comport completely with legal precepts of causation.

In Spring 2004, Ms. [REDACTED] presented to Christopher B. Michelsen, M.D. (Dr. Michelsen), an orthopaedic surgeon at Columbia-Presbyterian Medical Center, "for evaluation of bilateral knee pain." Pet. ex. I at 2. According to Dr. Michelsen, Ms. [REDACTED] complained that her knees were "becoming more stiff and weak since May of 1998." *Id.* Dr. Michelsen commented that by history, Ms. [REDACTED]'s symptoms "seem to have followed an hepatitis B immunization in April 1998." *Id.*

Upon examining Ms. [REDACTED]'s "cervical spine, shoulders and upper extremities," Dr. Michelsen appreciated "right shoulder impingement." Pet. ex. I at 2. Upon examining Ms. [REDACTED]'s knees, Dr. Michelsen appreciated "some posterior medial joint line tenderness." *Id.* Dr. Michelsen posited that Ms. [REDACTED] exhibited "possible autoimmune arthritis." *Id.* Dr. Michelsen contemplated a battery of diagnostic tests, including "an M[agnetic]R[esonance]I[maging] of the right knee." *Id.* The MRI showed "patellofemoral degenerative disease." Pet. ex. I at 1; *see also* Pet. ex. I at 3.

Dr. Michelsen's records offer scant support for a proposition that Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination caused Ms. [REDACTED]'s arthritis. As an preliminary matter, the special master notes that Dr. Michelsen's recitation of the chronology of Ms. [REDACTED]'s symptoms is not consistent with either the special master's determination that Ms. [REDACTED]'s

knee pain preceded Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination or the allegation that Ms. [REDACTED] did not experience knee pain until September 1998. *See* Pet. ex. 13, ¶ 4. Regardless, Dr. Michelsen's records do not express "a medical theory causally connecting" Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination with Ms. [REDACTED]'s arthritis. *Althen*, 418 F.3d at 1278. Dr. Michelsen remarked only that Ms. [REDACTED] suffered "possible autoimmune arthritis." Pet. ex. I at 2. It is axiomatic that "possible" is not "probable" or "more likely than not." Moreover, Dr. Michelsen did not relate Ms. [REDACTED]'s "possible autoimmune arthritis" to Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination. Indeed, Dr. Michelsen did not conclude anywhere in his records that Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination caused likely Ms. [REDACTED]'s arthritis. Further, Dr. Michelsen did not explain any association between MRI evidence of "patellofemoral degenerative disease," Pet. ex. I at 1, 3; "possible autoimmune arthritis," Pet. ex. I at 2; and Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination. Any other interpretation of Dr. Michelsen's records is simply conjecture. Therefore, the special master finds that Ms. [REDACTED]'s medical records do not establish by the preponderance of the evidence that Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination caused Ms. [REDACTED]'s arthritis.

Significant Aggravation

Ms. [REDACTED] presses in the alternative a significant aggravation claim. *See, e.g.*, Am. Pet.; Pet. ex. D; Pet. ex. 32. Congress desired specifically to extend the Program's compensation provisions to people with "possible minor events in" their "past medical history" who experience "serious cases of illness" related to vaccination. H.R. Rep. No. 99-908, pt. 1, at 15 (1986). Thus, Congress developed the concept of "significant aggravation." *Id.*; *see also* §§ 300aa-11(c)(1)(C); 300aa-14(a); 300aa-33(4). According to the Federal Circuit, the concept of significant aggravation is "one of the most slippery and difficult to apply" in Program practice. *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1105 (Fed. Cir. 1996)(*Whitecotton II)*.

In *Whitecotton II*, the Federal Circuit promulgated "the proper test for evaluating whether a petitioner has made out a *prima facie* significant aggravation claim under" a legal theory, commonly referred to as a Table claim, that confers a presumption of causation in certain circumstances. *Whitecotton II*, 81 F.3d at 1107. However, there exists still little, substantive, precedential jurisprudence regarding a significant aggravation claim under the actual causation theory. *See, e.g.*, *Williams v. Secretary of HHS*, No. 90-3091V, 1998 WL 156967 (Fed. Cl. Spec. Mstr. Mar. 18, 1998). Nevertheless, *Whitecotton II* is instructive to an extent. *Whitecotton II* suggests naturally that a petitioner pursuing a significant aggravation claim under the actual causation theory must show initially that after vaccination, petitioner sustained a significant aggravation of a preexisting condition. In addition, *Whitecotton II* suggests naturally that if a petitioner pursuing a significant aggravation claim under the actual causation theory is successful in showing that after vaccination, petitioner sustained a significant aggravation of a preexisting condition, petitioner must show then using traditional tort standards that the vaccination was responsible for the significant aggravation.

*See, e.g.*, *Whitecotton II*, 81 F.3d at 1107, citing *Reusser v. Secretary of HHS*, 28 Fed. Cl. 516, 527 (1993).

The statute enacting the Program defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). The Federal Circuit has ruled that the statutory definition of significant aggravation "implicitly requires a comparison of the person's pre-vaccination condition with the person's current, post-vaccination condition." *Whitecotton II*, 81 F.3d at 1107. The comparison dictates only seemingly rudimentary "factual assessments and determinations." *Id.* at 1108; *see also Haley v. Secretary of HHS*, No. 90-2727V, 1999 WL 476272 at *18 (Fed. Cl. Spec. Mstr. June 21, 1999)(*Whitecotton II* test is not "stringent").

The special master has found as a matter of fact that Ms. [REDACTED] exhibited numerous symptoms, including recurrent cold sores, "episodes of [questionable] sore throat, tactile temp[erature] [for] 2-3 days" and "fatigue," Pet. ex. 6 at 1, as well as knee pain, *see, e.g.*, Pet. ex. 7 at 1; 12 at 2, before her April 28, 1998 Hepatitis B vaccination. The symptoms continued after Ms. [REDACTED]'s April 28, 1998 Hepatitis B vaccination. *See, e.g.*, Pet. ex. 6 at 1; 7 at 1; 12 at 2. In August 1998, Ms. [REDACTED] suffered an illness diagnosed as "pneumonia" on "clinical" grounds, for which she received erythromycin. Pet. ex. 9 at 23-24. Also, in August 1998, a blood count revealed leukopenia.[6] *See* Pet. ex. 6 at 2; *see also* Tr. at 66, 118-19. For whatever reason, medical personnel did not note neutropenia until September 1999. *See, e.g.*, Pet. ex. 8 at 4; 11 at 5; *see also* Tr. at 32, 72-73. The neutropenia required only periodic monitoring. *See, e.g.*, Tr. at 164-65. Ms. [REDACTED] did not experience any bacterial infections or fungal infections that are common with chronic neutropenia. *See* Tr. at 70-71, 161, 166-67. A June 2005 blood count showed no evidence of neutropenia. *See* Pet. ex. L; *see also* Tr. at 24, 89, 124-25, 154; R. ex. D at 2 ("Counts improving").

Yet, whether the comparison of Ms. [REDACTED]'s pre-vaccination condition with Ms. [REDACTED]'s current condition yields a conclusion that Ms. [REDACTED]'s current condition constitutes a significant aggravation of Ms. [REDACTED]'s pre-vaccination condition, or whether the comparison of Ms. [REDACTED]'s pre-vaccination condition with Ms. [REDACTED]'s current condition yields a conclusion that Ms. [REDACTED]'s current condition does not constitute a significant aggravation of Ms. [REDACTED]'s pre-vaccination condition, is really of no consequence in this case. Ms. [REDACTED] depends upon Dr. Distenfeld's opinion as proof that her April 28, 1998 Hepatitis B vaccination caused a significant aggravation of a preexisting condition. *See, e.g.*, Pet. ex. D; Pet. ex. 32. And, as the special master has explained clearly, he does not credit Dr. Distenfeld's opinion.

## CONCLUSION

[6] Leukopenia is a "reduction in the number of leukocytes in the blood below about 5000 per cu. mm." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1022-23 (30th ed. 2003).

The special master determines that Ms. [REDACTED] has not established by the preponderance of the evidence that her April 28, 1998 Hepatitis B vaccination is the legal cause of her neutropenia, of her arthritis, or of the significant aggravation of any preexisting condition. Therefore, the special master rules that Ms. [REDACTED] is not entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The clerk of court shall send Ms. [REDACTED]'s copy of this decision to Ms. [REDACTED] by overnight express delivery.

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John F. Edwards
Special Master